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09/346,479 07/01/99 RITTER

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EXAMINER

HM22/0928

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ART UNIT

PAPER NUMBER

1651

DATE MAILED:

09/28/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/346,479

Applicant(s)

Ritter, Andrew

Examiner

Susan Coe

Group Art Unit  
1651



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-24 \_\_\_\_\_ is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-24 \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### DETAILED ACTION

1. Claims 1-24 are currently pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering live bacteria associated with yogurt for treatment of lactose intolerance, does not reasonably provide enablement for administering all types of live bacteria for treating lactose intolerance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The claims are drawn to administering all types of live bacteria for increasing lactose intolerance. However, the specification only teaches administering the bacteria that are associated with yogurt. Not all

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types of bacteria would be a beneficial supplement for the diet of a lactose intolerant individual. For example, US Pat. No. 5,952,021 explains that the unpleasant symptoms associated with lactose intolerance are due in large part to fermentation in the gut of undigested lactose by coliform bacteria. Administering these types of bacteria would not be a beneficial course of action for treatment of this disease; however, this course is encompassed by the breadth of applicant's claims. Without clear guidance for applicant's specification as to what types of bacteria are useful for treating lactose intolerance, a person of ordinary skill in the art would be forced to experiment unduly in order to discover bacteria that would be useful for the present invention. Thus, applicant's claims are not properly enabled for administering all types of live bacteria for the treatment of lactose intolerance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is indefinite because the claim does not state what values are associated with the "first dosage of a lactose...product," the "first predetermined number of days," the "predetermined amount of live...bacteria," the "second predetermined number of days," the

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“second dosage of the lactose...product,” and the “first predetermined point.” Without values for these limitations being stated in this claim, there is no way that an artisan would be able to definitely determine how to practice the invention as claimed in claim 1.

In addition, this claim also states that the dosages of the lactose containing product are increased. This is indefinite because it is not clear how large of an increase must be made in order to be encompassed by this limitation. Therefore, the metes and bounds of the claim cannot be definitely determined.

4. Claim 5 is indefinite because the phrase “said second predetermined point” lacks antecedent basis. No mention is made of this second point in the claims from which claim 5 depends; therefore, it is not clear when this point is supposed to take place in the treatment regimen claimed.

5. Claims 12 and 15 are indefinite because it is not clear when the “second predetermined point” is supposed to occur during treatment.

6. Claims 20 and 24 state that the administration of the first dosage is performed with dinner, the administration of the second dosage is performed with breakfast, and the administration of the lactose product is performed with breakfast and dinner. This is indefinite because from the previous claims the first and second dosages were the lactose containing products; however, claims 20 and 24 state that the lactose containing product is administered separately from the first and second dosages. Therefore, it is completely unclear what is being administered with the first and second dosages.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Dairy Science (1983), vol. 66, pp. 959-966)

The claims are drawn to a method of increasing lactose tolerance by administering live bacteria combined with a lactose containing product. A specific treatment regimen is described.

Kim teaches that administering milk with added *Lactobacillus acidophilus* increases lactose tolerance in subjects that are lactose intolerant. The subjects consuming the milk with added *L. acidophilus* showed a large improvement in the toleration of lactose (see Table 2 on page 962 and Table 3 on page 963). Therefore, Kim shows that it was known in the art at the time of the invention that administering *L. acidophilus* in conjunction with a lactose containing product increased lactose tolerance. However, Kim does not teach administering *L. acidophilus* and milk using the regimen claimed by applicant.

The treatment regimen to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule

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and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

8. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onwulata et al (American Journal of Clinical Nutrition (1989), vol. 49, pp. 1233-1237).

Onwulata teaches that administering yogurt increases lactose tolerance in lactose intolerant individuals. The yogurt contained live culture of *L. bulgaricus* and *S. thermophilus*. Therefore, Onwulata shows that it was known in the art at the time of the invention that administering bacteria in conjunction with a lactose containing product, yogurt, increased lactose tolerance. However, Onwulata does not teach administering yogurt using the regimen claimed by applicant.

The treatment regimen to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

9. No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 7:30 to 5:00 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC  
September 26, 2000

  
FRANCISCO PRATS  
PRIMARY EXAMINER